

## REMARKS/ARGUMENTS

Reconsideration of the application is requested.

Claims 13 - 38 are now in the application. Claims 1 - 12 have been canceled.

Claims 13, 15, 18, 19, 21, 24, and 25 have been amended.

More specifically, the claims have been amended in response to the Examiner's rejection and objections detailed on page 3 of the Office action. The Examiner's apparent suggestions have been adopted and the claims have been amended in an effort to satisfy the requirements of 35 U.S.C. § 112, first and second paragraphs. Should the Examiner find any further objectionable items, counsel would appreciate a telephone call during which the matter may be resolved.

In addition, the independent claims have been amended in order to clearly point out that the "supporting structure" of the claims is indeed a natural bone (human/animal origin), i.e., a spongy bone of human or animal origin. It is not a synthetically produced structure or an "engineered regenerative biostructure."

We now turn to the art rejection, in which claims 13, 14 and 22 have been rejected as being anticipated by Beam et al. (US 2003/0065400, hereinafter "Beam") under 35 U.S.C. § 102. We respectfully traverse on the basis of the amended claims.

Beam provides for an "engineered regenerative biostructure." It is a synthetically produced structure (i.e., "engineered") and, as such, it is not a bone of human or

animal origin (claims 13, 22) or a spongy bone of human or animal origin (claim 14).

Beam cannot anticipate claim 13, as amended.

Even though the demineralized bone matrix according to paragraphs 0041 and 0046 of Beam is a demineralized bone matrix and thus a body tolerable material, it is a synthetic matrix produced from bone particles and not a spongy bone of human or animal origin, even though it is demineralized.

At this point it is crucial to emphasize that all claims of the application are limited to the use of bone or human/animal origin - not "engineered or processed bone materials."

The above-mentioned clear limitation of the implant material to "not engineered", namely to materials from natural bones, eliminates US 4,553,272 to Mears as a relevant reference against claims 13 and 15.

The primarily important difference between Beam and the claimed invention consists not so much in the entirely different form, per se, of the channels in the implant body as defined by the invention, but in that the implant body in accordance with the invention is produced directly from bones of human or animal origin and thus without comminuting to small particles, without bonding agents and without pressing the particles into a specific implant shape.

It becomes entirely clear from the above explanations that the primarily essential difference between the invention and the materials mentioned in Beam does not lie

so much in the shaping process of the infusion channels and also not in the convex surface, thus convex top or cover surface, of the implant body but in the basic material of this implant body, which, according to the invention, is formed directly by a piece of a natural bone.

And this fact forms the basis of the instant invention. The claimed invention is clearly not shown or suggested by any of the prior art of record.

We now turn to the obviousness rejection in which claims 13, 14, and 16-23 have been rejected as being obvious over Beam and claims 13-15, 22, 24 have been rejected as being obvious over Beam and Mears under 35 U.S.C. § 103.

We respectfully traverse the Examiner's holding that the invention would have been obvious over either Beam or the combined teachings of Beam and Mears. The claimed invention as a whole would not have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

With regard to the Examiner's explanations, we do not disagree that implant bodies provided for similar purposes of implantation into bones or as a bone replacement and an impregnation with cell-solutions are indeed described in US 2003/0065400 to Beam. However, the material of the implant body disclosed therein which comes closest to the invention – even if it originally stems from a natural starting material from bones – is manmade and therefore has a uniform porous structure, which absolutely cannot be compared with the natural structure of a natural bone.

Beam describes precisely that the implant material he uses is not at all a natural and therefore spongy human or animal bone material per se that retains its natural structure. Rather, the bones are ground in accordance with Beam and, while providing blank spaces between the bone particles obtained therefrom, they are shaped on the outside such that they may be implanted, for example, in a void of a bone.

Therefore, in accordance with Beam, a porous artificial implant body is produced that is also accessible to an impregnation and has particles, connected to one another, from bone material.

In accordance with Beam, an implant body is produced and used, which has an entirely different inner structure than the bone into which the implant body is implanted. The material produced in accordance with Beam has absolutely nothing in common with a natural bone matrix.

It is precisely this completely different nature of the structure of the implant body of Beam, which, as found, ultimately leads to difficulties for quite understandable reasons when growing into a bone to be supplemented, since there is no structural similarity at all between the natural bone part to be replaced and the implant body material of Beam obtained by synthetic ways.

In contrast, the instant invention makes provision for a genuine bone particle material as an implant body – thus (material) not previously ground and then pressed by a shaping process – naturally free from irritating substances contained

therein, such as fat, cells and the like. The bone particle material, however, are bone pieces, which continue retaining their natural bone structure in an unmodified way, are formed according to the shape of the bone piece to be replaced and are impregnated with a cartilage cell suspension.

Compared to the implant bodies of Beam, these new implant bodies have the essential advantage that the natural bone structure is entirely present therein, thus has the greatest similarity in structure as possible, and therefore also affinity for bone structure of the natural bone of the patient to be replaced with the new natural bone implant body.

This greatly facilitates the in-growth of the natural implant body as defined by the invention compared to the in-growth of a synthetic implant body.

In summary, none of the references, whether taken alone or in any combination, either show or suggest the features of claims 13 and 25. Those claims are, therefore, patentable over the art and since all of the dependent claims are ultimately dependent thereon, they are patentable as well.

In view of the foregoing, reconsideration and the allowance of the claims are solicited.

Petition for extension is herewith made. The extension fee of \$ 555.00 for response within three months subsequent to the shortened statutory period of pursuant to Section 1.136(a) and in accordance with Section 1.17 is enclosed

herewith. Please charge any other fees which might be due with respect to  
Sections 1.16 and 1.17 to the Deposit Account of Lerner Greenberg Stermer LLP,  
No. 12-1099.

Respectfully submitted,

/Werner H. Stermer/

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WHS/lq

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